IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

ABBVIE INC. (a Delaware corporation); ALLERGAN, INC. (a Delaware corporation); DURATA THERAPEUTICS, INC. (a Delaware corporation); ABBVIE PRODUCTS LLC (a Georgia limited liability company); PHARMACYCLICS LLC (a Delaware limited liability company); ALLERGAN SALES, LLC (a Delaware limited liability company), *Plaintiffs*, v. MIKE HILGERS, in his official capacity as ATTORNEY GENERAL OF THE STATE OF NEBRASKA, *Defendant*.	**COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs AbbVie Inc., Allergan, Inc., Durata Therapeutics, Inc., AbbVie Products LLC, Pharmacyclics LLC, Allergan Sales, LLC (collectively "AbbVie" or "Plaintiffs"), by and through their undersigned attorneys, bring this action for declaratory and injunctive relief against the Attorney General of the State of Nebraska, challenging the applicability and constitutionality of L.B. 168. In support, AbbVie alleges as follows:

PRELIMINARY STATEMENT

1. AbbVie brings this lawsuit to challenge the constitutionality of L.B. 168. L.B. 168 effects an unconstitutional taking in violation of the Takings Clause of the Fifth Amendment. Nebraska's statute also violates the Supremacy Clause by impermissibly adding state-law

requirements for participating in the federal drug discount program established under Section 340B of the Public Health Service Act (the "340B statute"). In addition, L.B. 168 unlawfully discriminates against or unduly burdens interstate commerce in violation of the Commerce Clause, as established by Dormant Commerce Clause principles, and is unconstitutionally vague in violation of the Due Process Clause.

2. As such, L.B. 168 effects an unconstitutional taking in violation of the Takings Clause of the Fifth Amendment. It also violates the Supremacy Clause by impermissibly adding state-law requirements for participating in the federal 340B Program. In addition, L.B. 168 unlawfully discriminates against or unduly burdens interstate commerce and purports to regulate wholly out-of-state transactions in violation of the Commerce Clause.

3. L.B. 168 arises out of a long-running dispute about the requirements that the federal 340B program—a drug-pricing scheme—places upon drug manufacturers. In short, the federal 340B statute, 42 U.S.C. § 256b, establishes a comprehensive program that requires pharmaceutical manufacturers to offer their drugs at statutorily set and significantly reduced prices to a list of fifteen specifically enumerated types of healthcare providers known as "covered entities." Opting into the 340B Program and making these offers of drugs at the significantly reduced prices is required for manufacturers who want to participate in federal Medicaid and Medicare programs. *See* 42 U.S.C. §§ 256b, 1396r-8(a)(1), (5).

4. Under the 340B statute, manufacturers are required only to "offer" their drugs to covered entities at the 340B price—not "sell" them. 42 U.S.C. § 256b(a)(1). That is, the 340B statute requires only that manufacturers make an offer at a particular price to a particular set of covered entities but preserves the liberty of manufacturers to insist upon other non-price terms.

And commercial pharmacies, like Walgreens and CVS, are not among the 340B statute's list of entities entitled to an "offer" of the 340B price.

5. The federal 340B statute establishes a comprehensive program that is designed to help uninsured and low-income patients gain better access to prescription medications at discounted prices. As a condition of participating in the federal Medicaid program, pharmaceutical manufacturers must offer their covered outpatient drugs at deeply discounted prices to an enumerated list of "covered entities"—certain registered and specially identified safety net hospitals and clinics—that are expected to serve vulnerable patient populations. *See* 42 U.S.C. § 256b(a)(4). Federal law thus imposes an obligation on manufacturers to provide their drugs at 340B-discounted prices to certain specified covered entities in exchange for the federal government's commitment to subsidize Medicaid beneficiaries' drug expenses. Contract pharmacies are not mentioned in—let alone required by—the federal 340B statute.

6. For enforcement of its provisions, the 340B statute grants ***exclusive*** authority to the Secretary of the U.S. Department of Health and Human Services ("HHS"). *See* 42 U.S.C. § 256b(d). The statute leaves no role for states or other third parties to change the requirements of the federal 340B program or the conditions it imposes on manufacturers in return for participating in Medicaid and Medicare. Nor do states or other third parties have any authority to enforce the federal statute's requirements. The Supreme Court has held that third-party enforcement "would undermine the agency's efforts to administer" the 340B program and other related federal programs "harmoniously and uniformly." *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 119–20 (2011).

7. Because forcing manufacturers to transfer their drugs at discounted prices to covered entities raises serious constitutional concerns, Congress carefully limited the program to

ensure that manufacturers' discounted drugs would be used to help needy patients, and enacted certain safeguards to prevent the program from being abused for the benefit of other private parties. For example, in a statutory provision designed to prevent "diversion," Congress made clear that covered entities are not allowed to transfer manufacturers' drugs to anyone other than their own patients, prohibiting other entities from either participating in the 340B program or profiting from the sale of manufacturers' drugs at the 340B discounted price. *See* 42 U.S.C. § 256b(a)(5)(B).

8. Nevertheless, over the last decade covered entities have entered into novel contractual arrangements with commercial pharmacies (called "contract pharmacies") that have allowed those pharmacies to profit from the sale of manufacturers' drugs. Instead of serving the covered entities' uninsured and low-income patients, the for-profit contract pharmacies acquire manufacturers' drugs at the federally discounted price, sell them to patients (including indigent patients) at full price, and pocket the difference. Contract pharmacies accomplish this arbitrage through a complicated accounting system known as the "replenishment model," described in more detail below. The bottom-line result is that for-profit commercial pharmacies and the covered entities they contract with are able to pocket billions of dollars every year, splitting the profits at the expense of both manufacturers and the needy patients who are supposed to be served by the federal 340B program.

9. Neither contract pharmacies nor the replenishment model are features of the ordinary commercial drug-distribution system in the United States, outside the 340B context, where they are unauthorized by statute. AbbVie is involved in no other commercial arrangement using contract pharmacies or the replenishment model. Contract pharmacies and the replenishment model are creatures only of the federal 340B drug discount arbitrage regime.

10. In response to these abuses, manufacturers (including AbbVie) have adopted policies that limit when they will sell or facilitate the transfer of drugs at the 340B-discounted price to third-party commercial pharmacies. These policies recognize that the federal statute requires only that manufacturers "offer" their drugs at discounted prices to the covered entities ***themselves***. There is no additional requirement that manufacturers provide the drugs to whomever and wherever the covered entities may demand, and there is certainly no requirement that manufacturers allow commercial pharmacies to ***profit*** from the sale of their drugs at discounted prices under the federal 340B program.

11. Manufacturers' decisions to address these abuses resulted in litigation between manufacturers and HHS and, in early 2023, the U.S. Court of Appeals for the Third Circuit confirmed that the manufacturers' policies are lawful and permitted under federal law. Congress required manufacturers to offer their covered outpatient drugs at discounted prices in return for participating in Medicaid; it did not impose any additional obligation on manufacturers to provide their drugs to third-party commercial pharmacies, or to otherwise support arbitrage of their charitable discounts. Commercial pharmacies are not covered entities, and they are not entitled to benefit from the federal 340B program or access manufacturers' drugs at the 340B-discounted price. *See Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696 (3d Cir. 2023).

12. In May 2024, the United States Court of Appeals for the District of Columbia Circuit agreed with the Third Circuit's conclusion, holding that because "section 340B merely requires manufacturers to propose to sell covered drugs to covered entities at or below a specified monetary amount," the statute gives manufacturers freedom "to impose at least some delivery conditions." *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 460 (D.C. Cir. 2024). And

because conditions such as limiting delivery to "a single contract pharmacy designated by the covered entity" in no way impair a manufacturer's offer to sell drugs at the 340B-discounted price, the restrictions fall within the ambit of freedom manufacturers enjoy under the federal 340B statute. *Id.* at 462–64.

13. Many of Nebraska's sister states participated in the Third Circuit case as *amici curiae*, on the losing side. After that loss, many states turned to their own legislatures to propose and implement legislation to reach their desired 340B outcomes and attempt to impose requirements under the federal 340B statute that Congress chose not to impose. L.B. 168 is an example of one such piece of legislation and goes far beyond many statutes passed by Nebraska's sister states.

14. In particular, L.B. 168 seeks to change the requirements of when and to which entities manufacturers must provide 340B-discounted drugs as a condition of participating in Medicaid. *See* L.B. 168. L.B. 168 makes it unlawful for manufacturers to "directly or indirectly, deny, restrict, or prohibit the acquisition of any 340B drug by or delivery of any 340B drug to any location authorized by any 340B entity to receive such 340B drug, unless receipt of such 340B drug is prohibited by federal law." L.B. 168, § 3(1). The law effectively gives covered entities ***and pharmacies*** unfettered authority to take manufacturers' property for the benefit of private parties of their choice.

15. L.B. 168 violates the United States Constitution and should be enjoined.

16. ***First***, L.B. 168 deprives manufacturers of property without due process of law and results in an impermissible taking under the Fifth Amendment. Under the Fifth Amendment, made applicable to the states through the Fourteenth Amendment, neither the federal government nor the states have any authority to force A-to-B transfers of private property for the benefit of private

parties. *See Kelo v. City of New London*, 545 U.S. 469, 477 (2005) (explaining that "the sovereign may not take the property of A for the sole purpose of transferring it to another private party B, even though A is paid just compensation"). The federal government has defended the federal 340B statute on grounds that manufacturers are not being ***forced*** to transfer their property to for-profit pharmacies, but instead supposedly agreed to do so at the request of covered entities "voluntarily" in exchange for the benefit of participation in the federal Medicaid program. Nebraska has no such defense.

17. Nebraska purports to directly require manufacturers to transfer their property at steeply discounted prices to other private entities if those entities have ***third-party*** contracts that purport to allow them to access AbbVie's drugs at those deep discounts. L.B. 168's text makes clear that it seeks to regulate "acquisition of [] 340B drug[s]," defined as drugs purchased at the federally regulated discounted price. *See* L.B. 168, § 3; *id.* § 2(1). Nebraska has no authority to take private property for private use, and no authority to deprive AbbVie of its property without due process of law. By seeking to change the requirements for when drug manufacturers must provide 340B-priced drugs to third parties at the request of covered entities or pharmacies, the statute unlawfully appropriates private property for the private benefit of commercial pharmacies and does so without serving any valid public purpose. *See Horne v. Dep't of Agric.*, 576 U.S. 350, 370 (2015) (holding government's confiscation of portion of farmers' raisin crop for charitable or other purpose without just compensation was a *per se* taking).

18. ***Second***, even if L.B. 168 does not effect a taking, it is preempted by federal law under the Supremacy Clause. The doctrine of federal preemption requires that "any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield." *Felder v. Casey*, 487 U.S. 131, 138 (1988)). By seeking to limit the

federal offer requirements that manufacturers must make as a condition of participating in the federal Medicaid program, L.B. 168 unlawfully modifies the requirements of the federal 340B program. L.B. 168 impermissibly injects the Nebraska Attorney General and any county attorney, armed with state law penalties and other remedies, into what Congress intended to be an exclusively federal scheme. And, L.B. 168 also conflicts with the objectives of the 340B statute, imposing requirements on drug manufacturers that conflict with the actual requirements of the 340B statute, thereby raising the costs of Medicaid participation above those set by Congress and deterring manufacturers from that participation.

19. ***Third***, L.B. 168 violates the Commerce Clause, as interpreted by Supreme Court precedent applying the Dormant Commerce Clause doctrine. A state law cannot "directly regulate out-of-state transactions by those with no connection to the state." *Nat'l Pork Prods. Council v. Ross*, 598 U.S. 356, 376 n.1 (2023). L.B. 168 purports to do exactly that, because nowhere in the bill's text is there any requirement that the transactions it covers have ***any*** nexus to Nebraska. S*ee* L.B. 168, § 2(2) (defining "340B entity" by reference to the federal 340B statute, without limiting the definition to Nebraska covered entities); *see also* Neb. Rev. Stat. § 71-7438 (defining manufacturer as "***any entity*** engaged in manufacturing, preparing, propagating, processing, packaging, repackaging, or labeling a prescription drug. (emphasis added)). Nebraska is attempting to compel manufacturers to act in accordance with Nebraska law outside of Nebraska. Separately, "nondiscriminatory burdens on commerce . . . that . . . clearly outweigh the benefits of a state or local practice" also violate Dormant Commerce Clause principles. *Dep't of Revenue of Ky. v. Davis*, 553 U.S. 328, 353 (2008) (citing *Pike v. Bruce Church Inc.*, 397 U.S. 137, 142 (1970)). The burden L.B. 168 places on the national prescription drug industry and the viability

of the 340B program is excessive in relation to any legitimate benefits Nebraska could reap from it, because there are none—the effect of the bill is to actually harm 340B patients.

20. ***Fourth,*** in the alternative, if L.B. 168 does not effect an impermissible taking, is not preempted, and does not violate the commerce clause, then L.B. 168 is unconstitutionally vague. The purposes of the void for vagueness doctrine are to "give the person of ordinary intelligence a reasonable opportunity to know what is prohibited and provide explicit standards for those who apply [the statute]." *Video Software Dealers Ass'n v. Webster*, 968 F.2d 684, 689 (8th Cir. 1992) (internal quotations omitted) (modification in original). "It is a basic principle of due process that an enactment is void for vagueness if its prohibitions are not clearly defined." *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972) (collecting authority); *D.C. & M.S. v. City of St. Louis*, 795 F.2d 652, 653 (8th Cir. 1986) (same). In determining whether a statute is constitutionally vague, a court evaluates (1) whether the statute gives fair warning to those who are potentially subject to it and (2) does the statute do an adequate job of guarding against arbitrary and discriminatory enforcement. L.B. 168's mandate that manufacturers deliver 340B drugs to "any location authorized by any 340B entity" to receive them provides no fair or adequate warning as to what conduct is actually prohibited. Manufacturers are instead left to guess its meaning, including whether "location" means a for-profit entity, a non-profit, or even an individual or government agency, while facing corollary high risks of arbitrary and discriminatory enforcement.

21. AbbVie seeks a declaration that L.B. 168 is unconstitutional because it constitutes an unconstitutional taking. In the alternative, AbbVie seeks a declaration that L.B. 168 is unconstitutional because it is preempted by federal law, violates the Commerce Clause, or is unconstitutionally vague. AbbVie further seeks injunctive relief barring the Nebraska Attorney General or any county attorney from enforcing L.B. 168 against AbbVie.

PARTIES TO THE ACTION

22. AbbVie, Inc., a Delaware Corporation, is a global research-based biopharmaceutical company dedicated to addressing some of the world's most complex and serious diseases, and advancing medical science in areas such as immunology, oncology, and neuroscience. Since 2012, AbbVie, Inc. has participated in the federal 340B drug discount program, helping uninsured and vulnerable patients obtain access to the medications they need. AbbVie's headquarters are located in North Chicago, Illinois. AbbVie, Inc. is a signatory to 340B Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340B Pharmaceutical Pricing Agreements, with the U.S. Department of Health and Human Services ("HHS") Health Resources and Services Administration ("HRSA").[1]

23. Allergan, Inc., a Delaware Corporation, is a signatory to 340B Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340B Pharmaceutical Pricing Agreements, with HRSA.

24. Durata Therapeutics, Inc., a Delaware Corporation, is a signatory to 340B Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340B Pharmaceutical Pricing Agreements, with HRSA.

25. AbbVie Products LLC, a Georgia Limited Liability Company, is a signatory to 340B Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340B Pharmaceutical Pricing Agreements, with HRSA.

[1] On February 11, 2025, President Trump issued Executive Order 14210, titled "Implementing the President's 'Department of Government Efficiency' Workforce Optimization Initiative. *See* 90 Fed. Reg. 9,669. On March 27, 2025, HHS announced it intended to restructure, including by creating an Administration for a Healthy America ("AHA") which will have authority over, among other sub-agencies, HRSA. *See* Dep't of Health & Human Servs., *HHS Announces Transformation to Make America Healthy Again* (March 27, 2025), https://www.hhs.gov/press-room/hhs-restructuring-doge.html.

26. Pharmacyclics LLC, a Delaware Limited Liability Company, is a signatory to 340B Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340B Pharmaceutical Pricing Agreements, with HRSA.

27. Previously, Warner Chilcott Corporation merged with Allergan Sales, LLC and Allergan Sales, LLC is the surviving entity. Allergan Sales, LLC, a Delaware Limited Liability Company, is a signatory to 340B Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340B Pharmaceutical Pricing Agreements, with HRSA.

28. Defendant Mike Hilgers is the Attorney General of the State of Nebraska. L.B. 168 permits the Attorney General to "institute an action in the name of the State of Nebraska for an injunction or other process to restrain or prevent any violation of the 340B Contract Pharmacy Protection Act." *See* L.B. 168, § 4. This suit is brought against the Attorney General solely in his official capacity.

JURISDICTION AND VENUE

29. AbbVie's causes of action arise under 28 U.S.C. § 1331, 42 U.S.C. § 1983, and the United States Constitution.

30. The Court has subject matter jurisdiction under 28 U.S.C. § 1331, 28 U.S.C. § 1332, and 28 U.S.C. § 1343(a)(3).

31. The Court has authority to grant injunctive and declaratory relief under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202, and the Court's inherent equitable powers, including the power to enjoin the actions of state officials if contrary to the United States Constitution or federal law. *See Ex parte Young*, 209 U.S. 123, 159–60 (1908).

32. Venue is proper in this District under 28 U.S.C. § 1391(b) because this action challenges a Nebraska law that is applicable to AbbVie's sale and distribution of drugs at discounted prices under the federal 340B statute within this District. AbbVie sells and distributes

drugs to multiple 340B covered entities within this District, and these entities purport to maintain contract pharmacy arrangements. Venue is also proper because Defendants maintain offices, through which they would enforce the challenged law, in the city of Lincoln within this District.

GENERAL ALLEGATIONS

A. The 340B Drug Pricing Program.

33. This case concerns section 340B of the federal Public Health Service Act, which created the federal "340B program" as part of the authority granted in the Veterans Health Care Act of 1992. *See* 42 U.S.C. § 256b; *see also* Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967 (1992).

34. The purpose of the federal 340B program is to "reduce pharmaceutical costs for safety-net medical providers and the indigent populations they serve" by creating "a low-cost source of pharmaceutical medication for the indigent patients themselves." Connor J. Baer, *Drugs for the Indigent: A Proposal to Revise the 340B Drug Pricing Program*, 57 Wm. & Mary L. Rev. 637, 638 (2015) (footnote omitted).

35. Before Congress created the 340B program, individual manufacturers voluntarily provided their drugs at reduced prices to institutions that served needy and vulnerable patients. In 1990, Congress passed a statute called the Medicaid Rebate Act, which had the unintended consequence of creating disincentives for manufacturers to continue providing those voluntary discounts. H.R. Rep. No. 102-384, pt. 2, at 9–10 (1992). Through the Veterans Health Care Act, Congress remedied that unintended disincentive and established the federal 340B program, turning the manufacturers' previous voluntary support into a federal mandate.

36. The 340B statute requires that any manufacturer that participates in the federal Medicaid Drug Rebate Program must "offer" its covered outpatient drugs "for purchase" at deeply discounted prices to eligible "covered entities"—disproportionate share hospitals and other service

providers that are expected to serve predominantly low-income and vulnerable patients. 42 U.S.C. § 256b(a)(1).

37. The statute expressly limits participation in the 340B program to "covered entities." *See id.* § 256b(a)(4). The statute defines "covered entities" to include only organizations and service providers that predominantly serve low-income patients. The definition includes, for example, federally qualified health centers, children's hospitals, qualifying rural hospitals, and clinics that serve vulnerable patients. *Id*. For-profit commercial pharmacies are not included in the statutory list of "covered entities." *Id*. Nor does the 340B statute include any provision authorizing covered entities to purchase manufacturers' drugs and dispense them through commercial pharmacies. *See AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 60 (D. Del. 2021) ("It is hard to believe that Congress enumerated 15 types of covered entities with a high degree of precision and intended to include contract pharmacies as a 16th option by implication."), *aff'd sub nom. Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 703 (3d Cir. 2023).

38. The discounted 340B price for each of the manufacturer's drugs is calculated by subtracting the drug's Medicaid unit rebate amount from its Average Manufacturer Price, as determined under the federal Medicaid Drug Rebate Program, codified at section 1927 of the Social Security Act. 42 U.S.C. § 256b(a)(1)–(2) & (b). The resulting prices, called the 340B "ceiling prices," are significantly lower than the prices at which manufacturers sell their products to other purchasers. For the vast majority of innovator drugs, the mandatory discounts range from at least 23.1% to more than 99.9% of the average price in the market. *See* 42 U.S.C. § 1396r-8(c); 42 U.S.C. § 256b(a)(1). Many mandatory 340B ceiling prices are as little as one penny per unit of drug.

39. To indicate their agreement to participate in the federal 340B program and comply with its requirements, manufacturers sign a form contract with HHS, called the Pharmaceutical Pricing Agreement ("PPA"). That agreement is drafted by HHS. It has "no negotiable terms," and it "incorporate[s] the statutory obligations and record[s] the manufacturers' agreement to abide by them." *Astra*, 563 U.S. at 117–18.

40. The PPA imposes no obligation on participating manufacturers to sell discounted drugs to contract pharmacies. Nor does the PPA require manufacturers to cause their discounted drugs to be transferred to contract pharmacies. Nor does it grant covered entities any right to obtain access to manufacturers' drugs at discounted prices through contract pharmacies.

41. Both the PPA and the federal 340B statute are structured to prevent commercial parties from participating in the federal 340B program or profiting from the sale of manufacturers' drugs at discounted prices. Over the past decade, however, that is exactly what has happened as a result of covered entities entering into contractual relationships with commercial pharmacies. Under these arrangements, instead of using manufacturers' deeply discounted drugs to treat the indigent and uninsured patients that visit a covered entity and receive healthcare services from the covered entity itself, commercial contract pharmacies sell manufacturers' drugs at regular prices to pharmacy customers and then demand that their stocks be replenished with drugs purchased by the covered entity through the federal 340B program at discounted prices, pocketing the difference (the "spread") for their own financial benefit.

42. In recent years, commercial contract pharmacies have earned annually over $3.3 ***billion*** in "spread." *See* Eric Percher et al., Nephron Rsch. LLC, *The 340B Program Reaches a Tipping Point: Sizing Profit Flows and Potential Disruption*, at 3, 30–31 (2020) (concluding that $3.348 billion in 340B discounts were retained as profit by contract pharmacies in 2020 alone).

43. These abuses of the federal 340B program raise obvious concerns because the U.S. Constitution prohibits the government from forcing the transfer of property at confiscatory prices to private parties for their own private benefit. *See* U.S. Const. amend. V. They also violate the letter and spirit of the federal 340B statute. Congress designed the 340B statute with the intent that there would be a close nexus between the federal drug pricing program and its only valid public purpose—helping low-income and uninsured patients obtain access to medications at discounted prices. Consistent with that intent, the statute prevents covered entities from using manufacturers' drugs to generate commercial profits or letting the drugs be transferred or sold to benefit entities outside the program.

44. The statute expressly forbids "diversion" by prohibiting covered entities from selling or otherwise transferring any manufacturer's discounted drugs "to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B) ("With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity").

45. The statute also prohibits covered entities from receiving or causing "duplicate discounts or rebates." They may not obtain a 340B discount and cause a Medicaid rebate to be paid by the manufacturer for the same unit of drug. *Id.* § 256b(a)(5)(A).

46. The statute imposes an affirmative duty on the Secretary of HHS—through authority delegated to HRSA—to protect the program's integrity by "provid[ing] for improvements in compliance by covered entities . . . in order to prevent diversion" and violations of the statute's duplicate discount prohibition. *Id.* § 256b(d)(2)(A).

47. The statute provides mechanisms for resolving administrative disputes between manufacturers and covered entities through audits and a federal Administrative Dispute Resolution

("ADR") process. *See id.* § 256b(d)(l)(B)(v), (d)(3). Notably, HHS's HRSA recently issued a final rule setting forth additional details of the congressionally prescribed 340B ADR process. *See* 89 Fed. Reg. 28,643 (April 19, 2024). The final rule established a comprehensive scheme to resolve disputes between manufacturers and covered entities arising under the 340B statute. Under the rule, a "340B ADR Panel" within HRSA is tasked with resolving not only disputes about drug prices but also "claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price"—the exact issue L.B. 168 seeks to address. *See* 42 C.F.R. §§ 10.3, 10.21; *accord id.* § 10.22(c)(1) ("A manufacturer is responsible for obtaining relevant information or documents from any wholesaler or other third party that facilitate the sale or distribution of its drugs to covered entities."); 89 Fed. Reg. 28,649 (April 19, 2024) ("HHS agrees and has further modified § 10.21(a)(1) to further explain that an overcharge claim generally includes claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price."); *id.* at 28,644 ("[T]he 340B Program is related to drug pricing and drug distribution.").

48. The statute entrusts enforcement of the 340B statute *exclusively* to the Secretary of HHS and details what penalties may apply. *See* 42 U.S.C. § 256b(a)(5)(C)–(D), (d)(l)(B)(v), (d)(3). As the Supreme Court reasoned in *Astra*, Congress made HHS administrator of both the Medicaid Drug Rebate Program and the 340B program, and private enforcement by covered entities "would undermine the [HHS's] efforts to administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis." *Astra*, 563 U.S. at 119–20.

49. The 340B statute provides no private right of action to covered entities. *Id.* at 113–14.

50. Failure to comply with the statutory requirements under the 340B program may result in termination of the PPA (and the manufacturer's ability to participate in Medicaid), federal enforcement actions, and potentially the imposition of large civil penalties. *See* 42 U.S.C. § 256b(a)(5)(D), (d)(1)(B)(vi), (d)(2)(B)(v), (d)(3)(A).

B. The Growth in Contract Pharmacy Arrangements.

51. In 1996, HRSA issued non-binding guidance stating that the agency would not prevent covered entities ***that lacked an in-house pharmacy*** from entering into a contractual relationship with a ***single*** outside pharmacy to dispense covered outpatient drugs to the covered entity's patients. 61 Fed. Reg. 43,549 (Aug. 23, 1996). The guidance made clear that it "create[d] no new law and create[d] no new rights or duties." *Id.* at 43,550.

52. Guidance documents, such as the 1996 guidelines, are by definition general statements of policy that are non-binding, non-enforceable, and do not create any legal rights or obligations. They are intended instead to inform the public as to how HRSA intends to exercise its enforcement discretion.

53. In 2010, HRSA issued new non-binding guidance that radically changed how covered entities operated under the 340B program. The guidance stated, for the first time, that the agency would allow covered entities to enter into contractual relationships with an *unlimited* number of "contract pharmacies," even if the covered entity had an in-house pharmacy of its own. 74 Fed. Reg. 10,272 (Mar. 5, 2010).

54. Like the 1996 guidance, the 2010 guidance did not impose binding obligations on manufacturers. Indeed, HRSA again made clear that the non-binding guidance created no new rights and imposed no new obligations. *See id.* at 10,273 ("This guidance neither imposes additional burdens upon manufacturers, nor creates any new rights for covered entities under the law"). In other words, while HRSA indicated that it would not interpret the 340B statute to prohibit

covered entities from using multiple contract pharmacies, it did not purport to impose any obligation on manufacturers to transfer drugs to contract pharmacies or otherwise facilitate covered entities' use of contract pharmacies.

55. Following issuance of the 2010 guidance, covered entities dramatically increased their use of contract pharmacies, with a recent study reporting an increase of 12,000% between 2010 and 2024. *See* Elanor Blalock, *For-Profit Pharmacy Participation in the 340B Program: 2024 Update*, BRG 7 (Jan. 2025) ("BRG Report"), https://tinyurl.com/2k8daabf. This explosion in the use of contract pharmacies has been driven by the prospect of sharing in the outsized profit margins on manufacturer-subsidized 340B-discounted drugs. For example, in 2009 sales of 340B-priced drugs totaled just $4.2 billion, but by 2023 had increased by more than 30-fold to $124 billion. *See* Rory Martin & Harish Karne, *The 340B Drug Discount Program Grew to $124B in 2023*, IQVIA 2 (2024), https://tinyurl.com/ywkdbbju; Karen Mulligan, *The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments*, USC Schaeffer Cntr. For Health Pol'y & Econ. 5 (Oct. 2021) ("Mulligan"), https://tinyurl.com/y2fuv87u.

56. Similarly, the number of covered entities participating in the program jumped from around 15,000 in 2010 to more than 50,000 by 2020. *See* Mulligan, *supra*, at 4; U.S. Gov't Accountability Off., *Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements*, GAO-20-108, at 23 (2019), https://www.gao.gov/assets/d20108.pdf ("Given the weaknesses in HRSA's oversight, some hospitals that do not appear to meet the statutory requirements for program eligibility are participating in the 340B Program and receiving discounted prices for drugs for which they may not be eligible.").

57. Nor does the program's explosive growth correlate with an increase in indigent patients, or improvements in care. Indeed, since 2010, the percentage of uninsured patients in the

United States has fallen by nearly 38%. *See* Kenneth Finegold et al., U.S. Dep't of Health & Hum. Servs., Off. of the Assistant Sec'y for Planning & Evaluation, Trends in the U.S. Uninsured Population, 2010–2020, Issue Brief No. HP-2021-02, at 2 (Feb. 11, 2021), https://tinyurl.com/4rf9cm8t.

58. Contract pharmacies, which are predominantly large commercial pharmacy chains, do not operate like in-house pharmacies, do not themselves qualify as covered entities, and do not owe fiduciary duties to the covered entities. The relationships between covered entities and the for-profit, commercial pharmacies are governed by arm's-length contracts. Contract pharmacies are not "agents" of the covered entities; they are merely business partners. Importantly, these arrangements do not exist outside the context of the federal 340B program, as there is no other context in which commercial pharmacies are able to share in the "spread" generated by selling manufacturers' discounted drugs to their customers at full prices.

59. Contract pharmacy arrangements generally use one of two inventory models: (1) pre-purchased inventory or (2) replenishment.

60. A few contract pharmacies use the pre-purchased inventory model, in which a covered entity's 340B-purchased drugs are kept in stock at the contract pharmacy, and when filling prescriptions on behalf of that covered entity, the contract pharmacy uses the covered entity's 340B-purchased inventory.

61. Most contract pharmacies, however, use what is known as the "replenishment" model. The replenishment model is, as covered entities self-describe it, "an accounting mechanism" by which they retroactively match discounts for the pharmacy with previously (full price) dispensing events to customers. *See AbbVie et al. v. Murrill*, No. 6:23-CV-01307-RRS-CBW (W.D. La. June 6, 2024) ("*Murrill*"), Summ. J. Hr'g Tr. at 59-60 (Ron Connelly, counsel

for the Louisiana Primary Care Association); 61 Fed. Reg. 43,549, 43,555 (Aug. 23, 1996). In practice, the replenishment model permits the "transfer" of 340B-priced drugs to contract pharmacies with the full knowledge that those drugs will be sold to any customer who comes in the door, whether 340B-eligible or not.

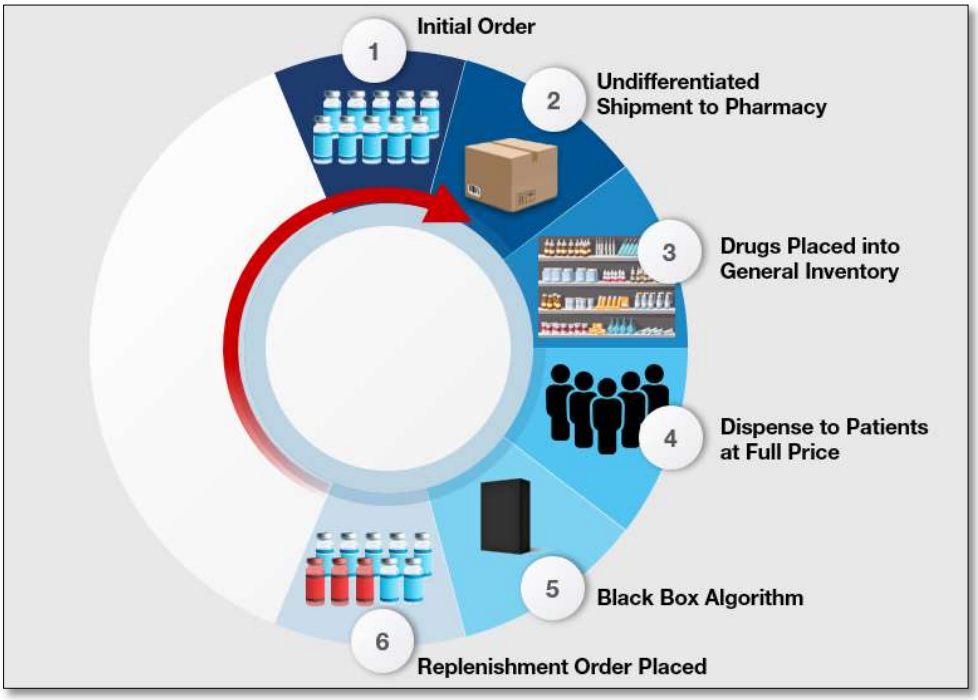

Figure 1. Replenishment Model Step-By-Step.

62. Under the replenishment model, no 340B-purchased drugs are kept in stock at the contract pharmacy. Instead, "the pharmacy has an initial stock of drugs" obtained through ordinary commercial purchases at the non-340B price (Figure 1, step 1). *See Murrill*, Summ. J. Hr'g Tr. at 60 (Ron Connelly, counsel for the Louisiana Primary Care Association). Initially, the contract pharmacy fills all prescriptions using its own non-340B purchased inventory (that is, full price inventory)—including those prescriptions issued by covered entities. As explained below, the pharmacy determines which previous dispenses were 340B eligible and once sufficient eligible dispenses for a particular drug accumulate, the covered entity orders additional quantities of that

drug at the federal 340B price (Figure 1, step 6). The covered entity directs AbbVie to transfer those drugs to the contract pharmacy to "replenish" the non-340B-priced drugs dispensed by the contract pharmacy on the covered entity's behalf (Figure 1, step 2). *See* Decl. of RADM Krista M. Pedley, Dir., Off. of Pharmacy Aff., HRSA, *Eli Lilly & Co. v. Becerra*, No. 1:21-cv-00081-SEB-MJD, ECF No. 125-2 ¶¶ 3–11 (S.D. Ind.). Sometimes the contract pharmacy actually places the order on behalf of the covered entity for more drugs at the federal 340B price.

63. Once the contract pharmacy receives the replenishment order, the 340B-priced drugs are "placed on the shelf, become[] 'neutral inventory,' and may be dispensed to any subsequent patient." (Figure 1, step 3). *See id.* at ¶ 11.

64. In other words, under the replenishment model, contract pharmacies do not keep a separate inventory of 340B-priced drugs but instead dispense drugs to both 340B and non-340B patients alike out of their general inventories. Nor do most contract pharmacies attempt to determine prior to or at the point of sale whether the patient is eligible for a 340B discounted drug. In almost all instances, contract pharmacies dispense the 340B-priced drugs to their customers at full price without knowledge as to whether, at the time of dispensing, that patient is a 340B-eligible patient (Figure 1, step 4). The pharmacy or a third-party administrator ("TPA") carries out a 340B determination at the back end, well after a drug has been dispensed (and likely consumed) by the patient. This determination is made using a black box algorithm (unknown by AbbVie) based on the contract pharmacy's own criteria, without any involvement from the covered entities (Figure 1, step 5). If those criteria are designed correctly, the post-sale determination may be able to calculate how many 340B-priced drugs AbbVie must sell. But in reality, the contract pharmacies' criteria often include prior patients, who no longer receive the 340B-discounted drugs at the pharmacy but that are included under a "once-a-patient-always-a-patient" approach, so the covered

entity and its pharmacies are able to maximize the arbitrage profits from the 340B program. As the D.C. Circuit observed, "[t]he covered entity, the pharmacy, and the third-party administrator often divvy up the spread between the discounted price and the higher insurance reimbursement rate. Each of these actors thus has a financial incentive to catalog as many prescriptions as possible as eligible for the discount." *Novartis*, 102 F.4th at 457–58.

65. Aside from diversion created by the pharmacies and covered entities' use of their own distorted criteria to mark otherwise 340B-ineligible sales as deserving the federally mandated low prices, the replenishment model encourages diversion by allowing covered entities to transfer federally discounted drugs to pharmacies, who are not "a patient of the entity." *See* 42 U.S.C. § 256b(a)(5)(B). Although HRSA interpreted the federal 340B statute to allow the use of pharmacies, it did so because "[w]e believe that the relationship between the covered entity and the contract pharmacy is one of agency." 61 Fed. Reg. 43,549, 43,554 (Aug. 23, 1996). Additionally, HRSA noted that the covered entity purchases the drug, retains title and responsibility for the drug even after directing shipment to the contract pharmacy. *Id.* at 43,553.

66. However, covered entities do not retain title to the drugs. As explained above, contract pharmacies (typically through a TPA) instruct covered entities to place orders—sometimes even placing the order itself, without going through a covered entity—of additional quantities of drugs at the discounted 340B price to "replenish" the general inventories that they will use to supply non-340B-eligible sales. Significantly, as a result of such replenishment, even though the drugs are purchased by or on behalf of covered entities, contract pharmacies effectively take title to the drugs. At no point in time does a covered entity take title to the drugs under this model. *See Sanofi Sues HHS, HRSA for Contract Details Between Covered Entities, Contract Pharmacies*, 340B Report (June 18, 2024), https://tinyurl.com/bdmx88wu (according to a covered

entity spokesperson, "in order for the replenishment model to work, 'the title to 340B drugs transfers to the contract pharmacy at the time it is taken into inventory.'"). AbbVie is also not aware of any instance where a contract pharmacy or covered entity represents that an agency relationship exists between them such that the contract pharmacy acts at the direction of a principal covered entity.

67. In practice, therefore, covered entities and contract pharmacies share in the "spread" generated by selling the drugs at higher prices to pharmacy customers and/or seeking full commercial reimbursement from the patients' insurance plans. For-profit, commercial pharmacies thereby obtain significant profits from selling the 340B covered outpatient drugs that manufacturers must offer to covered entities at deeply discounted prices.

68. By dramatically expanding the pool of individuals who can access the discounted drugs that covered entities can buy at discounted prices—including individuals who do not qualify as patients of the covered entity—covered entities and commercial pharmacies can obtain profits that extend far beyond Congress's intent when it created the 340B program. One study found that in 2018 alone, covered entities and their contract pharmacies generated approximately $64 billion in estimated gross profits from the purchase of manufacturers' drugs at mandated 340B prices. *See* BRG Report, *supra*, at 7.

69. When commercial pharmacies are brought into the program, there is a significantly greater risk that manufacturers' discounted drugs will be dispensed to individuals who are not "patients" of the covered entity. As HHS has found, contract pharmacy arrangements "create complications in preventing diversion" (for example, contract pharmacies cannot verify patient eligibility in real-time like a covered entity can). HHS Office of Inspector General, *Contract*

Pharmacy Arrangements in the 340B Program, OEI-05-13-00431, at 1 (2014) ("HHS Report"), https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf.

70. Because contract pharmacies often dispense 340B covered outpatient drugs from the same inventory as drugs dispensed to all other customers (and seek replenishment after the fact), the opportunities for unlawful distributions to ineligible patients increases, allowing covered entities and contract pharmacies to profit from the diversion that Congress intended to prohibit. *See* U.S. Gov't Accountability Off., *Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO-18-480, at 44 (June 2018), https://www.gao.gov/assets/d18480.pdf (noting that approximately two-thirds of diversion findings in HRSA audits involved drugs distributed at contract pharmacies); *id.* at 35, 43–44 (finding 45% of covered entities that responded to a recent GAO survey admitted they do not provide any discount to patients who use their contract pharmacies; and many of the remaining 55% reported rarely giving discounts to patients obtaining medicines through contract pharmacies).

71. Covered entities and commercial pharmacies reap windfalls from gaining access to manufacturers' drugs at deeply discounted prices under the federal 340B program, but uninsured and underinsured patients are not benefitting. *See* HHS Report, at 2 (finding that "some covered entities in our study do not offer the discounted 340B price to uninsured patients at their contract pharmacies"); Adam J. Fein, *The Federal Program that Keeps Insulin Prices High*, Wall. St. J. (Sept. 10, 2020), https://tinyurl.com/yxehpc7v (explaining that "almost half the U.S. pharmacy industry now profits from the 340B program, which is designed as a narrow support to certain hospitals," while patients "don't benefit," even though manufacturers have "practically given the product away"); Rory Martin & Kepler Illich, *Are Discounts in the 340B Drug Discount Program*

Being Shared with Patients at Contract Pharmacies?, IQVIA 12 (Sept. 27, 2022), https://tinyurl.com/2wdtuh52 ("The 340B Drug Discount Program as it exists today is a complex system of arbitrage . . . in which most vulnerable patients at contract pharmacies do not get drug discounts."); Lin JK et al., *Assessment of US Pharmacies Contracted with Health Care Institutions Under the 340B Drug Pricing Program by Neighborhood Socioeconomic Characteristics*, JAMA Health Forum 2 (June 17, 2022), https://jamanetwork.com/journals/jama-health-forum/fullarticle/2793530 (finding that contract pharmacy growth from 2011–2019 was concentrated in affluent and predominantly White neighborhoods and that the share of 340B pharmacies in socioeconomically disadvantaged and primarily non-Hispanic Black and Hispanic/Latino neighborhoods declined).

72. For example, the North Carolina Department of the State Treasurer published a recent report explaining that "some hospitals are using the 340B program to enrich themselves rather than to serve vulnerable communities," and "instead . . . expanded into wealthier neighborhoods with a higher percentage of insured individuals who pay more for the drugs." Dale R. Folwell, N.C. Dep't of State Treasurer, *Overcharged: State Employees, Cancer Drugs, and the 340B Drug Pricing Program*, N.C. State Health Plan 3, https://tinyurl.com/4cy8an69.

73. While commercial pharmacies are driving massive growth in the 340B program—at double-digit annual rates—charity care by hospitals has decreased. Commentators have noted, for example, that as the 340B program has grown at a remarkable rate, the total value of hospitals' uncompensated care has significantly declined. *See* Letter from Adam J. Fein to Hon. Lamar Alexander and Hon. Greg Walden in response to request for input on 340B drug pricing program, 7–8 (Oct. 30, 2020), https://drugchannelsinstitute.com/files/AdamFein-DrugChannels-340B-30Oct2020.pdf; Adam J. Fein, *EXCLUSIVE: 340B Program Purchases Reach $24.2 Billion—*

7%+ of the Pharma Market—As Hospitals' Charity Care Flatlines, Drug Channels (May 14, 2019), https://tinyurl.com/4z8dmjsv.

74. Both the New York Times and Wall Street Journal have run exposés describing the flaws in contract pharmacy arrangements, flaws that enable large scale arbitrage and damage the very communities that the federal 340B program was designed to help. *See* Katie Thomas & Jessica Silver-Greenberg, *Profits Over Patients: How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits*, NY Times (Sept. 24, 2022), https://tinyurl.com/3sbxuswa (describing how one 340B hospital "has been slashing services at Richmond Community while investing in the city's wealthier, white neighborhoods, according to more than 20 former executives, doctors and nurses"); Anne Wilde Mathews et al., *Many Hospitals Get Big Drug Discounts. That Doesn't Mean Markdowns for Patients*, Wall. St. J. (Dec. 22, 2022), https://tinyurl.com/yc2uc6yp ("The data show that hospitals often extend their 340B discounts to clinics in well-off communities, where they can charge privately insured patients more than those on Medicaid" which "raise questions about the program's growth and purpose").

75. A recent New York Times investigation into Apexus, the government contractor managing 340B drug pricing, exposed systemic price manipulation, lack of oversight, and financial exploitation within contract pharmacy arrangements—allowing for significant financial abuse at the expense of the communities the program was meant to protect. Apexus, which is responsible for negotiating better prices and access to mediations, has a direct financial incentive to expand the program and maximize hospital profits. Because Apexus "is allowed to collect a fee for almost every drug sold under the program," it has actively developed strategies to drive 340B sales and increase covered entity revenue. These strategies include training covered entities on how to maximize 340B revenue; operating a "purchasing optimization team" advising hospitals on which

drugs to generate the highest margins; and running a certification program teaching hospitals how to capture more patients and prescriptions under 340B. These tactics have prioritized profit generation over patient benefit, increasing Apexus's and covered entities' financial gains at the expense of patients, insurers, and manufacturers. Hospitals face no restrictions on which outpatient prescriptions they classify as 340B, allowing them to mine patient records from as far back as 36 months to claim additional patients under the program—even if those patients never directly benefit from the discounts. In some cases, hospitals have passed inflated drug costs onto patients instead of sharing the savings. *See* Ellen Gabler, *How a Company Makes Millions Off a Hospital Program Meant to Help the Poor*, N.Y. Times (Jan. 15, 2025), https://tinyurl.com/33ftpfdf.

C. Manufacturers' Response to HRSA's Overreach

76. AbbVie and other manufacturers have exercised their lawful right to decline covered entity requests that manufacturers provide their discounted 340B-priced drugs to an unlimited number of commercial pharmacies.

77. AbbVie has implemented initiatives making clear that it will not indiscriminately accept requests that it transfer 340B-discounted drugs to an unlimited number of third-party commercial contract pharmacies servicing covered entities.

78. As 340B abuse continued to grow, with covered entities seeking the provision of 340B-priced drugs to an excessive number of for-profit pharmacies—sometimes located more than 100 miles from the covered entity's location—AbbVie updated its policy to place reasonable limits around provision to contract pharmacies. Specifically, if a covered entity has its own in-house pharmacy, AbbVie's policy now is to only take orders for the in-house pharmacy. However, if a covered entity does not have an in-house pharmacy capable of dispensing to outpatients, AbbVie will take orders for direct delivery to one designated contract pharmacy, provided that the one

contract pharmacy is located within 40 miles of the HRSA registered covered entity parent site, and the covered entity submits limited claims data on 340B utilization for that pharmacy location. In addition, Grantee Covered Entities may use an unlimited number of contract pharmacies as long as the Grantee registers with 340B ESP™, a web-based platform made available to covered entities at no cost and submit claims data.[2] *See* Ltr. from E. Scheidler to 340B Covered Entities (Feb. 27, 2025), https://tinyurl.com/mr2rac4u.

79. In implementing its initiatives, AbbVie has confirmed that it will continue to offer "each covered entity" the ability to "purchase" its covered outpatient drugs "at or below the applicable ceiling" price set by statute. *See* 42 U.S.C. § 256b(a)(1). AbbVie is committed to ensuring that each hospital covered entity has at least one pharmacy location where it can receive shipments of discounted AbbVie medicines, and out of which it can dispense AbbVie's 340B-discounted drugs to qualifying patients. If a hospital covered entity is unable to identify an eligible contract pharmacy within 40 miles, AbbVie will work with the covered entity to identify a suitable alternative.

80. In addition to AbbVie, many other pharmaceutical manufacturers have adopted policies directed at addressing abuses of the 340B program by covered entities and contract pharmacies. Like AbbVie's, these policies do not refuse to supply drugs at discounted prices under the federal 340B program solely because the covered entity has an arrangement with a number of contract pharmacies; instead, they are directed at addressing program abuses.

[2] "Claims data," as used in the administration of the 340B program, refers to prescription-level information necessary to determine whether a drug is subject to a 340B discount, a Medicaid rebate, or both, and whether the recipient is a patient of a covered entity.

81. AbbVie's policy is not only consistent with those upheld by the Third and D.C. Circuits but also gives covered entities and contract pharmacies more convenience at its own expense. *See Sanofi*, 58 F.4th at 701; *Novartis*, 102 F.4th 452 at 463–64.

D. Litigation in Federal Courts

82. HHS initially recognized that it lacked authority to compel manufacturers to transfer drugs to contract pharmacies. *See* Tom Mirga, HRSA Says Its 340B Contract Pharmacy Guidance Is Not Legally Enforceable, 340B Report (July 9, 2020), https://340breport.com/hrsa-says-its-340b-contract-pharmacy/. HHS then reversed its position and attempted to impose a new obligation on manufacturers.

83. On December 30, 2020, HHS issued a final decision—labeled an "Advisory Opinion"—that for the first time ever purported to require manufacturers to facilitate the transfer of their products to for-profit commercial pharmacies. *See* U.S. Dep't of Health & Hum. Servs., Advisory Op. No. 20-06, Contract Pharmacies Under the 340B Program 1 (Dec. 30, 2020), https://tinyurl.com/35n4szy6. Various manufacturers brought suit in early 2021 to challenge this HHS decision.

84. On May 17, 2021, the government sent certain manufacturers "violation" letters purporting to enforce the 340B statute. AbbVie received a violation letter on October 17, 2022, stating that HHS had made a final determination that AbbVie's policy violated the 340B statute by not agreeing to transfer 340B discounted drugs to unlimited contract pharmacies because "AbbVie's actions have resulted in overcharges." *See* U.S. Dep't of Health & Hum. Servs., Violation Letter to AbbVie (Oct. 17, 2022), https://tinyurl.com/47ybp3kw.

85. While the December 30 decision was later withdrawn following a ruling from the federal district court for the district of Delaware, *see AstraZeneca*, 543 F. Supp. 3d at 47, the previously issued violation letters were not withdrawn.

86. Multiple states, through their Attorneys General, filed amicus briefs in the Third and D.C. Circuit Courts of Appeals in support of HHS, expressing disapproval of the manufacturers' policies. *See* Corrected Brief of Amicus Curiae States, *Novartis*, 102 F.4th 452 (No. 21-5299, filed May 23, 2022); Brief of Amicus Curiae, *Sanofi Aventis*, 58 F.4th 696 (3d Cir. 2023) (No. 21-3167, ECF No. 34).

87. On January 30, 2023, the Third Circuit issued a decision recognizing that Congress intentionally "chose not to" impose delivery-related obligations on manufacturers, explaining that the federal 340B statute's plain text suggests that Congress intended "one-to-one transactions between a covered entity and a drug maker without mixing in a plethora of pharmacies." *See Sanofi*, 58 F.4th at 704.

88. The Third Circuit further found that manufacturers' policies do not prevent covered entities from participating in the 340B program or entering into contractual relationships with commercial pharmacies. Under manufacturers' policies, covered entities "can still buy and dispense unlimited discounted drugs by having them delivered to an in-house or contract pharmacy." *Id*. at 703.

89. The Third Circuit rejected the argument that manufacturers were not permitted to address program abuses, such as diversion and duplicate discounting, by imposing restrictions on when they will transfer drugs to commercial pharmacies.

90. On May 21, 2024, the District of Columbia Circuit issued its own opinion endorsing the same view, holding that "section 340B merely requires manufacturers to propose to sell covered drugs to covered entities at or below a specified monetary amount." *Novartis*,102 F.4th at 460. As a result, as long as a manufacturer's policy "neither precludes [it] from making a bona fide 'offer' nor increases its contract 'price'"—such as only "deliver[ing] section 340B drugs to a

covered entity's in-house pharmacy or to a single contract pharmacy designated by the covered entity"—the condition is legitimate and may be enforced without running afoul of section 340B. *Id.* at 463–64.

91. In the face of those federal decisions, several states enacted their own laws trying to achieve what HHS could not. Those state laws—passed in Arkansas, Kansas, Louisiana, Maryland, Minnesota, Mississippi, Missouri, West Virginia, and others—try to limit manufacturers' ability to condition the federal offer by forcing them to transfer their drugs to an unlimited number of contract pharmacies at the 340B-discounted prices. A new round of federal litigation commenced. Manufacturers challenged the laws as unconstitutional on several grounds, and that litigation continues today.

92. The Eighth Circuit Court of Appeals upheld a state contract pharmacy law in Arkansas because the Court concluded that "[c]overed entities maintain title to the 340B drugs," and the "pharmacy becomes an agent of the covered entity." *Pharma. Res. & Manfs. of Am. v. McClain*, 95 F.4th 1136, 1142, 1144 (8th Cir. 2024). That is not true in Nebraska. Covered entities do not maintain title to 340B-discounted drugs provided to contract pharmacies, nor do contract pharmacies serve as the "agent of the covered entity." *Id.*

93. By contrast, the Southern District of West Virginia preliminarily enjoined West Virginia's contract pharmacy law, holding the law unconstitutionally conflicted with section 340B. *PhRMA v. Morrisey*, 2024 WL 5147643, at *7-12 (S.D. W. Va Dec. 17, 2024). Laws like Nebraska's L.B. 168 regulate "price, not delivery." *Id.* at *8. Under such laws, "[t]he question is only about what price the pharmacy and the covered entity will pay." *Id.* In other words, "the system is about delivery *at a given price*, not delivery *per se*." *Id.*

94. Other cases await decisions in district court, and multiple appeals are now pending before the Fourth and Fifth Circuit Courts of Appeals.

E. The Nebraska Law

95. After federal courts had already decided that the federal 340B statute grants manufacturers the freedom to adopt policies to combat abuse of the 340B program by contract pharmacies, Nebraska turned to its own legislature to enact a law that purports to take that freedom away.

96. The Nebraska legislature introduced L.B. 168—attempting to limit manufacturers' rights to condition federal 340B offers—on January 13, 2025. L.B. 168 passed Nebraska's Legislature on April 3, 2025, and on April 9, 2025 Governor Jim Pillen signed it into law. Since the legislature declared the law an emergency, L.B. 168 took immediate effect upon signing. *See* L.B. 168, § 7.

97. The text of L.B. 168 makes clear that compelling a private wealth transfer of 340B-priced drugs from one party to another, and changing the terms of the federal 340B program, are its regulatory objectives. The definitions of both "340B drug" and "340B entity," directly reference 42 U.S.C. § 256b, the 340B statute, making it apparent that the Nebraska statute cannot exist except in the context of the federal 340B program. *See* L.B. 168, §§ 2(1), (2). Put differently, if the federal program were repealed tomorrow, Nebraska's law would become a legally nullity.

98. L.B. 168 directly eliminates manufacturers' ability to adopt policies to prevent 340B abuse or prevent the taking of their own property by entities not otherwise entitled to it: "Any manufacturer . . . shall not, either directly or indirectly, deny, restrict, or prohibit the acquisition of any 340B drug by or delivery of any 340B drug to any location authorized by any 340B entity to receive such 340B drug, unless receipt of such 340B drug is prohibited by federal law." *Id.* at § 3(1).

99. "Location" is not defined in Nebraska's statute.

100. Further, Section 3 restricts manufacturers' right to request claims data: "Any manufacturer, agent or affiliate of such manufacturer, or third-party logistics provider shall not, either directly or indirectly, require any 340B entity to submit any data, including any claim data, utilization data, encounter data, medical data, purchasing data, or other data, as a condition for allowing the acquisition of any 340B drug by or delivery of any 340B drug to any 340B entity or to any location authorized by any 340B entity to receive such 340B drug, unless such data is required by federal law." *Id.* at § 3(2).

101. L.B. 168 tries to prevent manufacturers from collecting basic data that covered entities are already generating and sharing with their third-party vendors. *See id.* at § 3(2). That same data will allow manufacturers to monitor illegal diversion and duplicate discounting. It is also the sole means by which manufacturers may access the audit and ADR process. For similar reasons, a federal West Virginia court has already preliminarily enjoined West Virginia's similar law containing a similar prohibition. *Morrisey*, 2024 WL 5147643, at *7-12.

102. Although any state legislation attempting to modify manufacturers' requirements under the federal 340B statute is unconstitutional, L.B. 168 goes further than other previously enacted state laws. Nebraska purports to affirmatively grant covered entities' control over AbbVie's 340B-priced drugs to require their transfer to "any location authorized by any 340B entity to receive such 340B drug," directly conflicting with the federal 340B statute's prohibition against diversion, in violation of the Supremacy Clause. *See* L.B. 168, § 3(1); *see also* 42 U.S.C. § 256b(a)(5)(B) (providing that "a covered entity shall not resell or ***otherwise transfer*** the drug to a person who is not a patient of the entity." (emphasis added)). Additionally, L.B. 168 plainly expands the pool of entities authorized by Congress to receive drugs purchased at the 340B prices

by granting access to "any location authorized by any 340B entity to receive such 340B drug," which could expand well beyond just pharmacies in express disagreement with the Third and D.C. Circuits. *See, e.g.*, *Sanofi-Aventis*, 58 F.4th at 704 (disagreeing with HHS that "drug makers must deliver [340B priced drugs] where a covered entity demands, whether that be 'a neighborhood pharmacy' or 'the lunar surface.'"); *see also* L.B. 168, § 3(1).

103. The statute cites no source, under the 340B statute or elsewhere, that permits Nebraska to add requirements to the conditions for participating in the federal 340B program, or that authorizes Nebraska to establish an enforcement process for the Attorney General to seek "an injunction or other processes to restrain or prevent" alleged violations of the federal 340B requirements. *See* L.B. 168, § 4.

104. Put together, L.B. 168 authorizes the Nebraska "Attorney General or any county attorney" to institute an action "for an injunction or other processes" against manufacturers who fail to comply with covered entities and pharmacies' demands that they transfer 340B-priced drugs to any "location authorized by a 340B entity." *See* L.B. 168, §§ 3(1), 4.[3]

105. L.B. 168 purports to limit its scope in section (5), stating that "[n]othing in the 340B Contract Pharmacy Protection Act shall be construed or applied to conflict with federal law[.]" L.B. 168, § (5).

106. Yet, despite stating that it should not be construed to conflict with federal law, there is no way to read L.B. 168 in congruence with the 340B statute. There is no role for states to regulate 340B pricing, the use of the replenishment model and timing for submission of 340B

[3] The meaning behind L.B. 168's reference to "other processes" is unclear, but arguably could encompass even criminal enforcement of Nebraska's law. *See* L.B. 168, § 4. Similar laws enacted in several of Nebraska's sister states impose criminal penalties for comparable conduct. *See e.g.,* SD S.B. 154, § 1(17), 100th Leg., Reg. Sess. (2025) (imposing penalties ranging from a Class 1 misdemeanor to a Class 5 felony); Utah Code Ann. §§ 31A-2-308(9) (making violations of a similar statute a Class B misdemeanor).

claims, and the distribution of 340B-priced drugs to pharmacies or other "location[s]" who are not permitted as a matter of federal law to participate in the federal program and obtain access to manufacturers' drugs at discounted prices. The specific provisions of L.B. 168 conflict with Section 340B's requirements for drug manufacturers as well as its enforcement and penalty scheme.

107. AbbVie's compelled compliance is directly attributable to Nebraska's enactment of L.B. 168, which came into immediate effect upon the Governor's signature.

STANDING

108. AbbVie is injured by L.B. 168 because L.B. 168 imposes state-level requirements that directly conflict with and frustrate the federal 340B program. AbbVie is subject to conflicting obligations, compliance burdens, and potential enforcement actions. The law also forces AbbVie to provide its private property to another private party in a prohibited A-to-B wealth transfer. Moreover, the law subjects AbbVie to the Nebraska Attorney General and any county attorney's enforcement of the Act's requirements. Plaintiffs are signatories to 340B PPAs, and/or are successors-in-interest to executed 340B PPAs, with HRSA.

109. AbbVie's injuries are fairly traceable to L.B. 168 because the statute compels a private transfer of AbbVie's 340B-discounted drugs to private, for-profit commercial pharmacies. There is no recognized public use or purpose for such a transfer. That transfer would not occur but-for the operation of L.B. 168's prohibition on AbbVie's contract pharmacy policy. In addition, the statute seeks to impose new state law obligations on drug manufacturers participating in the 340B program beyond those required by the federal statute. Neither section 340B, nor any existing regulation, nor the PPA, contains these requirements. Moreover, the Act purports to grant the Nebraska Attorney General and any county attorney authority to enforce the Act in a way that violates federal law and would infringe on AbbVie's property rights.

110. A favorable ruling is likely to address AbbVie's injuries. Enjoining the provisions of L.B. 168 that unconstitutionally force the taking of manufacturers' private property for no public use would redress AbbVie's injuries because AbbVie's property would not be unconstitutionally taken, and AbbVie would not be exposed to state-imposed penalties for exercising its rights under the 340B program and the Constitution. Similarly, a declaratory judgment would redress AbbVie's injuries because AbbVie would not be exposed to enforcement actions and accumulating penalties.

BASIS FOR INJUNCTIVE RELIEF

111. "Irreparable harm occurs when a party has no adequate remedy at law, typically because its injuries cannot be fully compensated through an award of damages." *Facility Guidelines Inst., Inc. v. UpCodes, Inc.*, 677 F. Supp. 3d 955, 975 (E.D. Mo. 2023) (quoting *Gen. Motors Corp. v. Harry Brown's, LLC*, 563 F.3d 312, 319 (8th Cir. 2009)). Moreover, where costs are not recoverable because the government-defendant enjoys sovereign immunity from monetary damages, irreparable harm generally exists. *See Ala. Ass'n of Realtors v. Dep't of Health & Hum. Servs.*, 141 S. Ct. 2485, 2489 (2021) ("The moratorium [on collecting rent during COVID-19 pandemic] has put the applicants, along with millions of landlords across the country, at risk of irreparable harm by depriving them of rent payments with no guarantee of eventual recovery."); *see also Iowa Utls. Bd. v. FCC*, 109 F.3d 418, 426 (8th Cir. 1996) ("The threat of unrecoverable economic loss . . . does qualify as irreparable harm.").

112. Effecting an unconstitutional taking of AbbVie's private property in a forced transfer to another private party for no recognized public use or purpose constitutes an irreparable injury. *See Laclede Gas Co. v. St. Charles Cnty.*, 713 F.3d 413, 419-20 (8th Cir. 2013) (affirming grant of preliminary injunction on takings claim). A taking occurs each and every time AbbVie is

required against its own volition to transfer its drugs at the 340B-discounted price to a commercial pharmacy for the private benefit of that for-profit pharmacy.

113. Further, if L.B. 168 is not enjoined as applied to AbbVie, AbbVie would be exposed to additional state law requirements as a condition of participating in the federal 340B program and would risk violating L.B. 168 simply by performing its federally mandated functions. *See Brooks v. Francis Howell Sch. Dist.*, 599 F. Supp. 3d 795, 805 (E.D. Mo. 2022) ("Well-settled law holds that the loss of [constitutional] freedoms, even for minimal periods of time, 'unquestionably constitutes irreparable injury.'" (quoting *Elrod v. Burns*, 427 U.S. 347, 373 (1976))). A party may be irreparably injured in the face of the threatened enforcement of a preempted law. *See, e.g.*, *Craig v. Simon*, 980 F.3d 614, 617–18 (8th Cir. 2020); *see also Bank One, Utah v. Guttau*, 190 F.3d 844, 847–48 (8th Cir. 1999) (concluding that where the plaintiff proves preemption and "that it will suffer irreparable harm if the State is not enjoined from enforcing [the preempted law], then the question of harm to the State and the matter of the public interest drop from the case, for [the plaintiff] will be entitled to injunctive relief no matter what the harm to the State, and the public interest will perforce be served by enjoining the enforcement of the invalid provisions of state law."); *Rogers Grp., Inc. v. City of Fayetteville*, 629 F.3d 784, 785, 789–90 (8th Cir. 2010) (affirming preliminary injunction in preenforcement suit alleging that a municipality's ordinance was beyond its powers under state law and finding a sufficient threat of irreparable harm where the plaintiff "admit[ted] that the Quarry currently operated at a level the Ordinance permitted" but "testified that the Ordinance would prevent the Quarry from expanding"); *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 160 (2014) (concluding that a plaintiff has standing to "bring a preenforcement suit when he has alleged an intention to engage in a course of conduct arguably affected with a constitutional interest, but proscribed by a statute,

and there exists a credible threat of prosecution thereunder." (internal quotation marks and citation omitted)); *Ass'n for Accessible Medicines v. Ellison*, 2023 WL 8374586, at *6–7 (D. Minn. Dec. 4, 2023) (granting motion for preliminary injunction when the statute at issue was already in effect and movants were in compliance).

114. If drug manufacturers such as AbbVie are required to provide their drugs to contract pharmacies, the magnitude of the economic loss is beyond the capacity of Nebraska to compensate with damages. Discounted purchases under the program reached approximately $66.3 billion for fiscal year 2023 in the U.S. *See* Health Res. & Servs. Admin., *2023 340B Covered Entity Purchases* (Oct. 2024), https://tinyurl.com/56nzphvm.

115. Further, Nebraska's total anticipated net revenue receipts for the upcoming biennium FY 2025-27 is $6.9 billion. *See* Gov. Jim Pillen, *State of Nebraska Executive Budget 2025-2027 Biennium* 7 (2025), https://das.nebraska.gov/budget/publications/docs/2025-2027/2025/ExecutiveBudgetinBrief2025-2027Biennium.pdf. That means that even if Nebraska's entire anticipated biannual revenue were dedicated to covering AbbVie's losses from the sales the state now compels, it would still come up short. As such, the ordinary legal remedy of damages would be insufficient. *See Eastern Enters. v. Apfel*, 524 U.S. 498, 521 (1998) (plurality op.) (noting that the Supreme Court has considered injunctive relief where there is a "lack of a compensatory remedy").

116. Prospective injunctive relief is appropriate because of the ongoing nature of the infringement of constitutional rights resulting from L.B. 168. The law effects a repeated and ongoing mandatory private wealth transfer of AbbVie's 340B-discounted drugs to private, for-profit commercial pharmacies for the private benefit of that pharmacy and for no recognized public use, in violation of the United States' Constitution. The law deprives AbbVie and other

manufacturers of their federal rights under the actual terms of the 340B program. And, L.B. 168 threatens to impose significant penalties upon manufacturers if they do not capitulate to Nebraska's attempt to modify the terms of that federal program. The deprivation of constitutional rights constitutes irreparable injury for purposes of a preliminary injunction. *Planned Parenthood of Minn., Inc. v. Cit. for Community Action*, 558 F.2d 861, 867 (8th Cir. 1977) (citing Wright & Miller, Federal Practice and Procedure § 2948 (1973)); *see also Nichols v. Moyers*, 2013 WL 2418218, at *2 (E.D. Mo. June 3, 2013) ("[Plaintiff's] ongoing inability to exercise her fundamental [constitutional] right . . . shows that she is threatened with irreparable harm in the absence of injunctive relief."); Wright & Miller, Federal Practice and Procedure § 2948.1 n. 26 (2d ed. 1995) (collecting cases).

117. Granting injunctive relief here would not harm the State. It is well settled that a state "cannot be irreparably harmed by an inability to enforce an unconstitutional law." *Toigo v. Dep't of Health & Senior Servs.*, 549 F. Supp. 3d 985, 995 (W.D. Mo. 2021); *Rodgers v. Bryant*, 942 F.3d 451, 458 (8th Cir. 2019) (upholding the lower court's "imposition of a . . . preliminary injunction" where it found, among other things, that "preventing [a state] from enforcing a law that is plainly unconstitutional would cause no injury." (internal quotation marks omitted)); *Pavek v. Simon*, 467 F. Supp. 3d 718, 762 (D. Minn. 2020) ("[A] State has no interest in enforcing laws that are unconstitutional and an injunction preventing the State from enforcing the challenged [unconstitutional] statute does not irreparably harm the State." (internal quotation marks and citation omitted) (cleaned up)); *Hispanic Interest Coalition of Ala. v. Governor of Alabama*, 691 F.3d 1236, 1249 (11th Cir. 2012). Moreover, there is no evidence that uninsured and needy patients—in Nebraska or anywhere else—benefit from the use of contract pharmacies, and

Nebraska has no legitimate interest in enriching commercial pharmacies at the expense of manufacturers and patients.

118. Granting injunctive relief would be in the public interest. The public has no legitimate interest in enforcing unconstitutional laws, particularly those that force a private property transfer for no public use or purpose. *See Fernandez v. St. Louis Cnty., Missouri*, 538 F. Supp. 3d 888, 903 (E.D. Mo. 2021) ("The public has no interest in enforcing an unconstitutional ordinance." (internal quotation marks and citation omitted)). By contrast, the public has a strong interest in preventing states from imposing unconstitutional requirements that force the transfer of private property for the private benefit of private commercial parties. *Nichols*, 2013 WL 2418218, at *2 ("[T]he Eighth Circuit has made clear that 'it is always in the public interest to protect constitutional rights.'" (quoting *Phelps–Roper v. Nixon*, 545 F.3d 685, 690 (8th Cir.2008))). Further, the public has a strong interest in enforcing federal law and not permitting states to change the requirements for participation in federal healthcare programs.

FIRST CLAIM FOR RELIEF

Prospective Injunctive Relief and Declaratory Relief – Violation of Takings Clause, U.S. Const. amend. V, cl. 4

119. AbbVie re-alleges and incorporates by reference all of the allegations contained in the preceding paragraphs of this complaint as though set forth fully herein.

120. The Takings Clause of the Fifth Amendment provides: "[N]or shall private property be taken for public use, without just compensation." U.S. Const. amend. V.; *see also Chicago, Burlington & Quincy Ry. v. Chicago*, 166 U.S. 226, 234–35 (1897) (incorporating and making applicable to states the Takings Clause of the Fifth Amendment through the Due Process Clause of the Fourteenth Amendment).

121. The Takings Clause extends to both real and personal property. *Horne*, 576 U.S. at 358. It is not limited to instances when the government physically appropriates property for its own use through eminent domain. A taking can also occur through legislation and regulation that sufficiently deprives a user of its property rights. *See E. Enters. v. Apfel*, 524 U.S. 498, 529 (1998).

122. Under the Constitution, the government has no authority to force A-to-B transfers of private property for the benefit of private parties. *See Kelo*, 545 U.S. at 477 (explaining that "the sovereign may not take the property of *A* for the sole purpose of transferring it to another private party *B*, even though *A* is paid just compensation"). Such private takings are always unconstitutional, since "[n]o amount of compensation can authorize such action." *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 543 (2005); *Calder v. Bull*, 3 U.S. (3 Dall.) 386, 388 (1798) (explaining that "[i]t is against all reason and justice" to allow government to "take[] property from A. and give[] it to B").

123. "Whenever a regulation results in a physical appropriation of property, a *per se* taking has occurred." *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 149 (2021). Statutes or regulations that mandate the physical transfer of personal property from one private party to another private party amount to an unconstitutional taking with or without just compensation.

124. L.B. 168 appropriates AbbVie's property rights in its drugs for the private benefit of for-profit, commercial pharmacies and covered entities. On its face, Nebraska's L.B. 168 prohibits manufacturers from "directly or indirectly, deny[ing], restrict[ing], or prohibit[ing] the acquisition of any 340B drug by or delivery of any 340B drug to any location authorized by any 340B entity to receive such 340B drug." L.B. 168, § 3(1). Under statutory text, manufacturers could even be held liable for refusing to transfer drugs ordered by a covered entity to a potentially unlimited number of locations "authorized" by the covered entity (not necessarily even ones

contracting with a covered entity, and textually they need not even necessarily ***be*** pharmacies). If Nebraska requires manufacturers to provide their drugs to other private entities, including contract pharmacies, at below-market prices—by purporting to add that as a state-law obligation attached to the federal 340B scheme—then Nebraska is engaged in an impermissible per se violation of the Constitution's Takings and Due Process Clauses.

125. In the alternative, L.B. 168 effectuates a partial regulatory taking.

126. In *Penn Central Transportation Co. v. New York City*, 438 U.S. 104, 124 (1978), the Supreme Court recognized that a regulatory taking requires consideration of a flexible three-factor test: (1) the economic impact of the regulation, (2) the extent to which the regulation has interfered with investment backed expectations, and (3) the "character of the governmental action."

127. L.B. 168's purported requirement that manufacturers transfer their drugs to commercial pharmacies is constitutionally impermissible because it requires the physical acquisition of AbbVie's drugs by another private party for no public purpose or use; imposes significant financial losses on AbbVie and other manufacturers; interferes with drug manufacturers' reasonable investment backed expectations; and serves no valid government purpose because it deprives manufacturers of the full use and control of their property on a continual basis for the commercial benefit of private parties.

SECOND CLAIM FOR RELIEF

Declaratory/Injunctive Relief – Federal Preemption Under the Supremacy Clause, U.S. Const. art. VI, cl. 2

128. AbbVie re-alleges and incorporates by reference all of the allegations contained in the preceding paragraphs of this complaint as though set forth fully herein.

129. Under the Supremacy Clause of the Constitution, federal law is "supreme . . . , any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. As a result, federal statutes and regulations properly enacted and promulgated can nullify or "override[] a [conflicting] state law" or local actions. *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 353 (2000). In other words, "where a state statute conflicts with, or frustrates, federal law, the former must give way." *Forest Park II v. Hadley*, 336 F.3d 724, 731-33 (8th Cir. 2003) (cleaned up) (concluding that the remedy plaintiff requested for a violation of state law "would be legally unwarranted if the state statutes are preempted"); *Oberkramer v. IBEW-NECA Serv. Ctr.*, 151 F.3d 752, 756 (8th Cir. 1988) (concluding the district court properly dismissed state common law claims which were preempted by federal law).

130. Preemption can take multiple forms: express preemption, field preemption, and conflict preemption. *Forest Park II*, 336 F.3d at 732.

131. Conflict preemption occurs where it is impossible for a private party to comply with both state and federal law and also where "the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby*, 530 U.S. at 372–73 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)) (alterations omitted); *see also Forest Park II*, 336 F.3d at 733.

132. By restricting manufacturers' right to condition their federal offer, L.B. 168 imposes obligations beyond those established by Congress. Federal law does not grant pharmacies unilateral authority to dictate the terms of purchase of manufacturers' discounted drugs. L.B. 168 unlawfully removes manufacturers' right to set the terms for sales of 340B-priced drugs, forcing them to transfer their discounted drugs to any location authorized by a covered entity—even if it contradicts federal law.

133. Congress specifically defined which entities qualify for 340B discounts and intentionally chose not to mandate manufacturer participation in contract pharmacy arrangements. *See AstraZeneca*, 543 F. Supp. 3d at 60. Nebraska has no lawful authority to force manufacturers to transfer their drugs under the 340B program at deeply discounted prices to any entity, let alone commercial pharmacies that do not qualify as covered entities under the federal program. The carefully delineated obligation for manufacturers to offer 340B priced drugs to covered entities is lawfully imposed by federal law solely as a condition of a manufacturer's participation in federal healthcare programs. To the extent that Nebraska seeks to impose, through L.B. 168, any substantive obligation on manufacturers beyond what federal law requires, that state law obligation is preempted by federal law. Further, L.B. 168 grants commercial pharmacies and covered entities unchecked authority over manufacturers' offers without federal authorization. This unrestricted power creates diversion risks, contradicting federal safeguards and forcing manufacturers to support it.

134. The replenishment model results in diversion, which the federal statute forbids. *See* 42 U.S.C. § 256b(a)(5)(B). Thus, L.B. 168 is preempted to the extent it expressly and impliedly protects the use of the replenishment model, a practice clearly in conflict with Congress' mandates.

135. Additionally, federal law does not prohibit manufacturers from requesting claims data. Indeed, manufacturers cannot satisfy federal audit requirements without providing data-backed "reasonable cause" for HRSA to audit a covered entities' 340B compliance. 61 Fed. Reg. 65,406, 65,407 (Dec. 12, 1996) (providing that "audits are to be performed only when there is a reasonable cause to believe that there has been a violation" of the 340B statute). L.B. 168 imposes an absolute ban on requiring claim or utilization data, preventing manufacturers from engaging in federally permitted compliance efforts. *See* L.B. 168, § 3(2). By imposing a ban on the collection

of claims data, L.B. 168 creates an irreconcilable conflict with federal law and obstructs the objectives of the federal 340B program, including by obstructing manufacturers' ability to access federal audits of covered entities' 340B compliance.

136. It is foundational constitutional law that States may not regulate Congress's creations. *See McCulloch v. Maryland*, 17 U.S. (4 Wheat.) 159 (1819) (Marshall, C.J.). A state law may not change the conditions for participation in the federal Medicare and Medicaid programs. Any attempt by Nebraska to regulate in this area impermissibly changes the requirements for participating in the federal 340B program and nullifies the "natural effect" of federal law. *Crosby*, 530 U.S. at 372–73.

137. Another type of implied preemption is field preemption. Field preemption occurs when Congress "occupies an entire field" of regulation so comprehensively that it has "foreclose[d] any state regulation in the area, even if it is parallel to federal standards." *Arizona v. United States*, 567 U.S. 387, 401 (2012); *see also Crosby*, 530 U.S. at 372–73. Field preemption also occurs where Congress intends "to foreclose any state regulation in the area, even if it is parallel to federal standards." *Arizona*, 567 U.S. at 401.

138. The 340B program is a comprehensive federal healthcare program. Every detail of the 340B program is determined by federal law, including the pricing and the consequences for participating manufacturers who fail to comply with the 340B statute's requirements. "Price regulation is exclusively controlled by the federal statute, and state enforcement of it would necessarily intrude on the federal scheme." *Morrisey*, 2024 WL 5147643, at *10.

139. L.B. 168 prohibits manufacturers from declining to deliver their drugs to contract pharmacies ***at a particular price***. *See Morrisey*, 2024 WL 5147643, at *9. Manufacturers violate laws like L.B. 168 "not by withholding drugs from contract pharmacies, but by refusing the 340B

discount when delivering [their] drugs to those pharmacies." *Id.* That the state law defines the drugs in issue as "340B drug[s]" confirms that L.B. 168 is a price regulation: "***Price*** is what distinguishes between an 'ordinary drug' and a 340B Program drug—a fact that seems to be reflected in the [Nebraska] statute itself." *Morrisey*, 2024 WL 5147643, at *9 (emphasis added).

140. Moreover, L.B. 168 was enacted in response to manufacturers' policies, which according to HRSA and HHS result in overcharges. But the federal statute does not authorize state regulation concerning 340B pricing and who is entitled to access manufacturers' drugs at discounted 340B prices. It leaves no room for states to interfere with the carefully designed 340B program. *See Arizona*, 567 U.S. at 401 (holding that where Congress has occupied the field, state laws that impose additional obligations are preempted).

141. L.B. 168 directly interferes with the established federal oversight structure by undermining federal enforcement authority. L.B. 168 purports to grant the Nebraska Attorney General a substantive role in the 340B program's administration and enforcement, despite and in conflict with the comprehensive compliance and enforcement regime Congress provided. The Nebraska Attorney General is not the entity Congress tasked with enforcement of the 340B statute. "Congress . . . made HHS administrator of both the Medicaid Rebate Program and 340B Program." *Astra*, 563 U.S. at 120. State enforcement "would undermine the agency's efforts to administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis." *Id.*

142. Congress not only defined who was entitled to administer the 340B program (the Secretary of HHS, who has lawfully delegated the authority to HRSA), it also delineated which tools were available to the Secretary to ensure compliance. The 340B statute defines which audit procedures and ADR mechanisms are available under the 340B program for handling disputes among manufacturers and covered entities concerning program compliance. *See* 42 U.S.C.

§ 256b(d)(l)(B)(v), (d)(3). Likewise, Congress outlined the penalties that apply to manufacturers who violate the statutory requirements under the 340B program and engage in "overcharging." *See id.* § 256b(d)(l)(B)(vi), (d)(2)(B)(v). Nebraska's attempt to install an alternative compliance and enforcement regime, with different regulators and distinct penalties, conflicts with the procedures detailed in the 340B statute and the lawfully promulgated federal rules implementing the statute.

143. The difficulty of complying with varying state regulatory frameworks only increases as more states pass new and different laws relating to the 340B program. As of filing, 13 states have passed contract pharmacy laws akin to L.B. 168. State laws such as those passed by Maryland, West Virginia, Mississippi, Minnesota, Missouri, Arkansas, Kansas, Louisiana, New Mexico, Utah, North Dakota, South Dakota, and now Nebraska, have material differences among and between themselves, complicating compliance by manufacturers and subjecting manufacturers to different and varying enforcement. *Compare* West Va. Code § 60A-8-6a (extending similar prohibitions to an "agent, or affiliate" of a manufacturer), La. Rev. Stat. § 40:2883 (prohibiting a manufacturer from "prevent[ing] or interfer[ing] with ***any patient's choice*** to receive such drugs from the 340B entity" (emphasis added)), NM H.B. 78, § 1(A)(4), 57th Leg., 1st Sess. (2025) (covering only entities "receiv[ing] federal grant funding"), *and* L.B. 168, § 3(1) (compelling delivery to "***any location***" authorized by a covered entity (emphasis added)). Some states, like Nebraska, prohibit requiring the submission of claims data while others do not. *Compare* Md. Health Occupations Code § 12-6C-09.1 (prohibiting restrictions on "delivery" or "acquisition" of "340B drugs") *with* L.B. 168, § 3(2) (restricting the collection of "any claim data, utilization data, encounter data, medical data, purchasing data, or other data") *and* UT S.B. 69, § 1(2)(b)(ii), 66th Leg., Gen. Sess. (2025) (restricting the collection of "any claim data, utilization data, or

information about a 340B entity's contracts with a third party"). Some states even criminalize manufacturer's conduct. *See* Utah Code Ann. §§ 31A-2-308(9) (making violations of the statute a Class B misdemeanor).

144. As these laws continue to accrete, administration of the 340B program and compliance with a patchwork of state laws may become untenable, with potential catastrophic effects for the nationwide prescription drug industry. *See* Adam J. Fein, *EXCLUSIVE: The 340B Program Soared to $38 Billion in 2020—Up 27% vs. 2019*, Drug Channels (June 16, 2021), https://tinyurl.com/4jdjhh7u (analyzing HRSA data to find the 340B program accounted for "16% of . . . total U.S. gross sales of brand-name drugs at list prices" in 2020).

THIRD CLAIM FOR RELIEF

Declaratory/Injunctive Relief – Commerce Clause, U.S. Const. art. 1 § 8

145. AbbVie re-alleges and incorporates by reference all of the allegations contained in the preceding paragraphs of this complaint as though set forth fully herein.

146. Central to our federal constitutional structure is the principle that "all States enjoy equal sovereignty." *Shelby Cnty. v. Holder*, 570 U.S. 529, 535 (2013). "A basic principle of federalism is that each State may make its own reasoned judgment about what conduct is permitted or proscribed within its borders, and each State alone can determine what measure of punishment, if any, to impose on a defendant who acts within its jurisdiction." *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 422 (2003) (citation omitted). This basic principle manifests in the several constitutional provisions that limit the power and authority of the states in relation to each other. *See, e.g.*, U.S. Const. art. I, § 10 (denying certain powers states otherwise might enjoy as sovereign nations); art. IV, § 1 (Full Faith and Credit Clause); art. IV, § 2, cl. 1 (Privileges and Immunities Clause); art. IV, § 2, cl. 2 (interstate extradition).

147. The Commerce Clause—which grants Congress the "Power . . . To regulate Commerce . . . among the several States," U.S. Const. art. I, § 8, cl. 3—also implicitly limits the extraterritorial authority of the States. The Supreme Court has held that the Commerce Clause prohibits states from directly "control[ling] commerce occurring wholly outside [its] boundaries." *Healy v. Beer Inst.*, 491 U.S. 324, 335–36 (1989); *see also Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579 (1986).

148. The Court recently clarified the reach of its "dormant" Commerce Clause jurisprudence, holding that state regulation of conduct within its borders that may also have an "extraterritorial effect" in other states are not categorically barred. *Nat'l Pork*, 598 U.S. at 374. But the Court also made clear that it did not disturb its prior precedent finding state laws unconstitutional where they "directly regulated out-of-state transactions by those with no connection to the State." *Id.* at 376 n.1 (citing *Edgar v. MITE Corp.*, 457 U.S. 624, 641–43 (1982)). As a result, a state statute may violate the dormant Commerce Clause in three ways: if it (1) "clearly discriminates against interstate commerce in favor of in-state commerce," (2) "imposes a burden on interstate commerce that outweighs any benefits received," or (3) "has the practical effect of extraterritorial control on interstate commerce." *Grand River Enters. Six Nations, Ltd. v. Beebe*, 574 F.3d 929, 942 (8th Cir. 2009).

149. L.B. 168 runs afoul of dormant Commerce Clause principles on all three fronts.

150. ***First***, L.B. 168 discriminates against interstate commerce in favor of in-state commerce. The central aim of Nebraska's law is to privilege state hospitals and pharmacies over out-of-state manufacturers by forcing the manufacturers to provide drugs at significantly reduced prices to hospitals and pharmacies that would not otherwise be entitled to reduced prices under

federal law. That significantly burdens out-of-state manufacturers like AbbVie for the direct benefit of in-state entities by compelling AbbVie to extend them bargain basement pricing.

151. Nebraska cannot articulate any valid justification for discriminating against out-of-state manufacturers. As detailed above, compelling AbbVie to transfer more drugs at reduced costs to contract pharmacies does not benefit 340B patients—it serves only to create arbitrage profits for commercial pharmacy chains.

152. The Nebraska Legislature's use of a federal program to benefit the in-state covered entities and contract pharmacies ***themselves*** at the expense of out-of-state manufacturers like AbbVie, would "amount[] to 'simple economic protectionism'" that the Supreme Court recently affirmed to be an illegitimate legislative interest. *Nat'l Pork*, 598 U.S. at 372 (quoting *Brown-Forman Distillers Corp. v. New York State Liquor Auth.*, 476 U.S. 573, 580 (1986)). By protecting local economic interests at the expense of interstate commerce, Nebraska engages in economic protectionism, precisely what the dormant Commerce Clause doctrine aims to prevent.

153. ***Second***, L.B. 168 imposes a burden on interstate commerce that outweighs any conceivable benefit to in-state commerce. *Davis*, 553 U.S. at 353 (2008).

154. L.B. 168 places an improper thumb on the scale and tilts the bargaining power in favor of in-state pharmacies and covered entities at the expense of out-of-state manufacturers.

155. In addition to directly regulating out-of-state transactions, L.B. 168 violates dormant Commerce Clause principles because courts will strike down "nondiscriminatory burdens on commerce . . . that . . . clearly outweigh the benefits of a state or local practice." *Davis*, 553 U.S. at 353 (2008).

156. L.B. 168 poses a very high burden on the 340B program and the national prescription drug industry as a whole. Forcing manufacturers across the country to transfer their

discounted drugs to ***any*** "location" authorized by ***any*** covered entity will result in transactions that may be fully permissible in the state where they actually occur but become subject to enforcement actions in Nebraska. Therefore, L.B. 168 effectively compels manufacturers to sell discounted drugs nationwide based on Nebraska's mandates, imposing an extraterritorial economic burden.

157. But even if passed to help ensure 340B-eligible patients receive discounts on their prescription medications, L.B. 168 will actually have the opposite effect. Manufacturers, no longer able to impose conditions on who actually receives their drugs, will be unable to stop abuses that result in covered entities requiring "insured patients to pay *more* for their prescriptions at contract pharmacies so the covered entity can generate 340B funds." Peter J. Pitts & Robert Popovian, *340B and the Warped Rhetoric of Healthcare Compassion*, Food & Drug L. Inst. Update Mag. (Fall 2022) (emphasis added), https://tinyurl.com/yc6fnc5c. L.B. 168 provides no legitimate benefit to the State of Nebraska and thus cannot outweigh the high burden it places on the national drug industry and the 340B program itself.

158. ***Third***, L.B. 168 has the practical effect of extraterritorial control on interstate commerce. *Styczinski v. Arnold*, 46 F.4th 907, 912 (8th Cir. 2022); *see Healy*, 491 U.S. at 324 (concluding that "a statute that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State's authority and is invalid regardless of whether the statute's extraterritorial reach was intended by the legislature"). Covered entities often enter contract pharmacy arrangements with pharmacies located outside the state. For example, a Nebraska covered entity may have contract pharmacies in Minnesota. And a Minnesota covered entity may have contract pharmacies in Nebraska.

159. L.B. 168 bars ***any*** "manufacturer, agent or affiliate of such manufacturer, or third-party logistics" from "directly or indirectly, deny[ing], restrict[ing], or prohibit[ng] the acquisition

of any 340B drug by or delivery of any 340B drug to ***any location*** authorized by any 340B entity[.]" L.B. 168, § 3(1) (emphasis added); *see also* § 3(2) (preventing collection of claim data from "***any location*** authorized by any 340B entity to receive such 340B drug" (emphasis added)). The statute makes no effort to limit the location to authorized 340B entities within the state of Nebraska. These provisions permit the Attorney General to use L.B. 168 to regulate out-of-state manufacturers that conduct minimal to no business within the state.

160. L.B. 168 thus prohibits ***any*** manufacturer across the country from imposing conditions to the transactions between itself and ***any*** location authorized by any 340B entity to receive such 340B drug, regardless of whether such manufacturer or entity has any nexus to Nebraska.

161. Indeed, on its face, the Nebraska law could govern a transaction between a drug manufacturer located in Illinois, its wholesaler in Kentucky, and a California pharmacy that contracts with a covered entity in Florida and dispenses the drug to a Nebraska resident. Such broad reach results in Nebraska's improper interference with interstate commerce in violation of dormant Commerce Clause doctrine.

FOURTH CLAIM FOR RELIEF

Declaratory/Injunctive Relief – Due Process Clause, U.S. Const. art. XIV

162. AbbVie re-alleges and incorporates by reference all of the allegations contained in the preceding paragraphs of this complaint as though set forth fully herein.

163. The Due Process Clause of the Fourteenth Amendment provides that no State may "deprive any person of life, liberty, or property, without due process of law." U.S. Const. amend. XIV, § 1. "Due process has two requirements": "that laws provide notice to the ordinary person of what is prohibited and that they provide standards to law enforcement officials to prevent arbitrary and discriminatory enforcement." *Postscript Enter. v. Whaley*, 658 F.2d 1249, 1254-55

(8th Cir. 1981); *see also United States v. Davis*, 588 U.S. 445, 451 (2019) ("Vague laws contravene the first essential of due process of law that statutes must give people of common intelligence fair notice of what the law demands of them."). While a civil statute is held to less stringent standards, even laws which impose only civil consequences must still undergo a "stringent vagueness test." *Video Software*, 968 F.2d at 6899-90 ("The degree of constitutional vagueness depends partially on the nature of the enactment.") (citing *Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 499 (1982)); *see also Carolina Youth Action Project; D.S. by and through Ford v. Wilson*, 60 F.3d 770, 781 (4th Cir. 2023); *Manning v. Caldwell for City of Roanoke*, 930 F.3d 264, 273 (4th Cir. 2019) (en banc).

164. L.B. 168's provision that prohibits a manufacturer from "deny[ing], restrict[ing], or prohibit[ing] the acquisition of a 340B drug by, or delivery of any 340B drug to ***any location*** authorized by any 340B entity to receive such 340B drug" is unconstitutionally vague and does not provide drug manufacturers with fair notice as to what conduct is actually prohibited and invites arbitrary and discriminatory enforcement.

165. "Location" is not defined in L.B. 168. And the statute gives no hint as to how a manufacturer can determine whether a "location" is "authorized by any 340B entity to receive such 340B drug." Absent further specificity, the requirement of delivery to a "location" under L.B. 168's broad terms could require delivery of 340B-priced drugs virtually anywhere.

166. L.B. 168 purports to grant covered entities and their contract pharmacies—private parties—the sole discretion to determine which ***other*** private parties may receive 340B drugs at *which* location, and accordingly when manufacturers violate the law by failing to oblige covered entities and their contract pharmacies' dictates. Nebraska's law contains no limitation or guidance to covered entities and their contract pharmacies governing whether and how they may direct

manufacturers to deliver 340B drugs to any authorized "location." Accordingly, they may order delivery to literally anywhere, regardless of whether it is "the lunar surface, low-earth orbit, or a neighborhood pharmacy." *Novartis*, 102 F.4th 452, at 458. Yet that understanding, once advanced by HHS, has been held arbitrary and withdrawn. *Id*. Covered entities and contract pharmacies are fiercely resistant to providing or making their contractual agreements available to manufacturers or publicly—compounding the vagueness problem because manufacturers have no idea whether and how a particular "location" is authorized.

167. L.B. 168 is unconstitutionally vague on its face. The provision requiring manufacturers to deliver 340B drugs to any "location authorized by any 340B entity to receive" them fails to provide fair notice as to what is prohibited. Persons of common intelligence must guess at its meaning and may well offer vastly different yet reasonable interpretations of its scope.

PRAYER FOR RELIEF

WHEREFORE, AbbVie prays for the following relief:

1. A declaration, order, and judgment declaring that L.B. 168 effects an impermissible taking of AbbVie's property for private benefit;
2. A declaration, order, and judgment holding L.B. 168 unlawful because it is preempted by federal law and unconstitutional under the Supremacy Clause;
3. A declaration, order, and judgment declaring that L.B. 168 violates the Commerce Clause;
4. A declaration, order, and judgment declaring that L.B. 168 is unconstitutionally vague and violates the Due Process Clause;
5. A declaration, order, and judgment holding that the 340B statute does not require drug manufacturers to provide 340B pricing to contract pharmacies or transfer or

cause their discounted covered outpatient drugs to be transferred to contract pharmacies;

6. A preliminary and permanent injunction enjoining the Nebraska Attorney General from enforcing L.B. 168;

7. An award of all costs and attorneys' fees pursuant to any applicable statute or authority; and

8. Any other relief that this Court deems just and proper.

Dated: April 9, 2025

Respectfully submitted,

/s/ Jason W. Grams

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